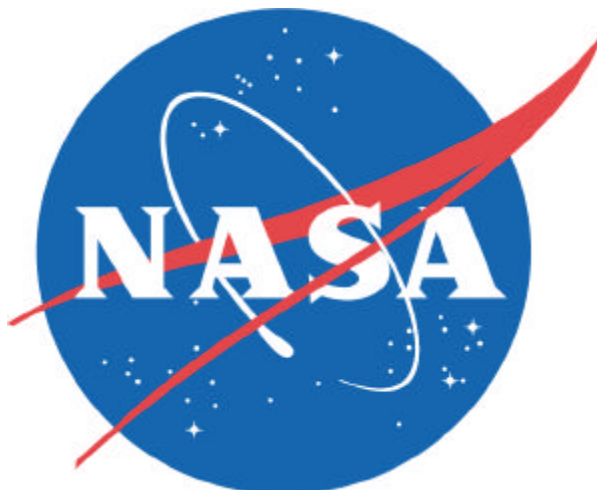


Office Work Instruction

HOWI 1800-AM001 REV. E
May 1, 2001

Responsible Office: AM/Office of the Chief Health & Medical Officer

Subject: Agency Medical Policy and Guidance Formulation
(Human Space Flight)



OFFICE WORK INSTRUCTION

AGENCY MEDICAL POLICY and
GUIDANCE FORMULATION
(Human Space Flight)

Original Approved and Signed by:

Dr. Arnauld E. Nicogossian
Associate Administrator, Office of Life and
Microgravity Sciences and Applications

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DOCUMENT HISTORY LOG

Status (Baseline/ Revision/ Canceled)	Document Revision	Effective Date	Description
Baseline		02/01/99	
Revision	A	04/30/99	Incorporates changes made in response to comments from the Code U review and the DNV Pre-Assessment Report.
Revision	B	08/17/99	Incorporates changes to eliminate letter version designations and correct titles on reference documents.
Revision	C	11/01/99	Administrative change to reflect the fact that the Medical Policy Document is no longer in draft but is signed and official, and that it is a reference document, not a quality record, remove reference to Occupational Health NPC 1800, reflect the use of NMI 8900 since the draft NPD 8900 is not complete, and make the person responsible for the process the Director, Office of Health Affairs since there is currently no PD for the position of Program Executive in Aerospace Medicine and Psychology.
Revision	D	02/29/00	Removes draft status for NMI 8900, Astronaut Medical and Dental Observation Study and Care Program to NPD 8900, Astronaut Medical and Dental Observation Study and Care Program
Revision	E	05/04/00	Administrative changes to achieve agreement in section 5, 6 and 7 in the language for quality record identification. Addition of outside process link to the approval process of NPD, NPG, and NPC documents in step 4 of section 5 and 6.
Admin Update	E	05/01/01	Administrative change to transfer Responsible Office from Code U to Code AM. Former Code U # was U012.

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1. Purpose

This Office Work Instruction (OWI) defines the process for the formulation and approval of medical policy and Guidance for NASA's human space flight program.

2. Scope and Applicability

This OWI applies to the activities of Office of Life and Microgravity Sciences and Applications (OLMSA) staff in formulating NASA medical policies and guidance that are under the purview of the NASA Medical Policy Board (MPB). These medical policies and guidance are stated in the MPB's Medical Policies Document (MPD). Within OLMSA, the Office of Health Affairs (OHA) has lead responsibility for NASA medical policy and guidance for human space flight.

3. Definitions

- 3.1 Chief Medical Officer (CMO) – The senior NASA medical officer provided by OLMSA to guide all aspects of Agency medical policy as defined in NPD 1800.2, NASA Occupational Health Program.
- 3.2 Executive Secretary, MPB The Director, OHA or his/her representative serves as Executive Secretary of the MPB. The Executive Secretary is responsible for preparing and distributing meeting minutes and maintaining, updating or revising the MPD.
- 3.3 Medical Policy Board (MPB) - A board consisting of physician representatives from across the agency which formulates NASA medical policy and guidance for human space flight. A full description of the MPB is provided in NASA Policy Charter 1152.59F, NASA Medical Boards in Support of Space Flight Operations. The CMO is the Chairperson of the Medical Policy Board (MPB).
- 3.4 Medical Policies Document (MPD) - A NASA Headquarters document that states the medical policies established by the MPB. The MPB is responsible for this document.

4. Reference Documents

- 4.1 NPC 1152.59, NASA Medical Boards in Support of Space Flight Operations
- 4.2 NPD 8900, Astronaut Medical and Dental Observation Study and Care Program
- 4.3 NPD 7100.8, Protection of Human Research Subjects
- 4.4 NPD 8900, Astronaut Medical and Dental Observation Study and Care Program
- 4.5 Medical Policy Board Medical Policy Document Revision IV

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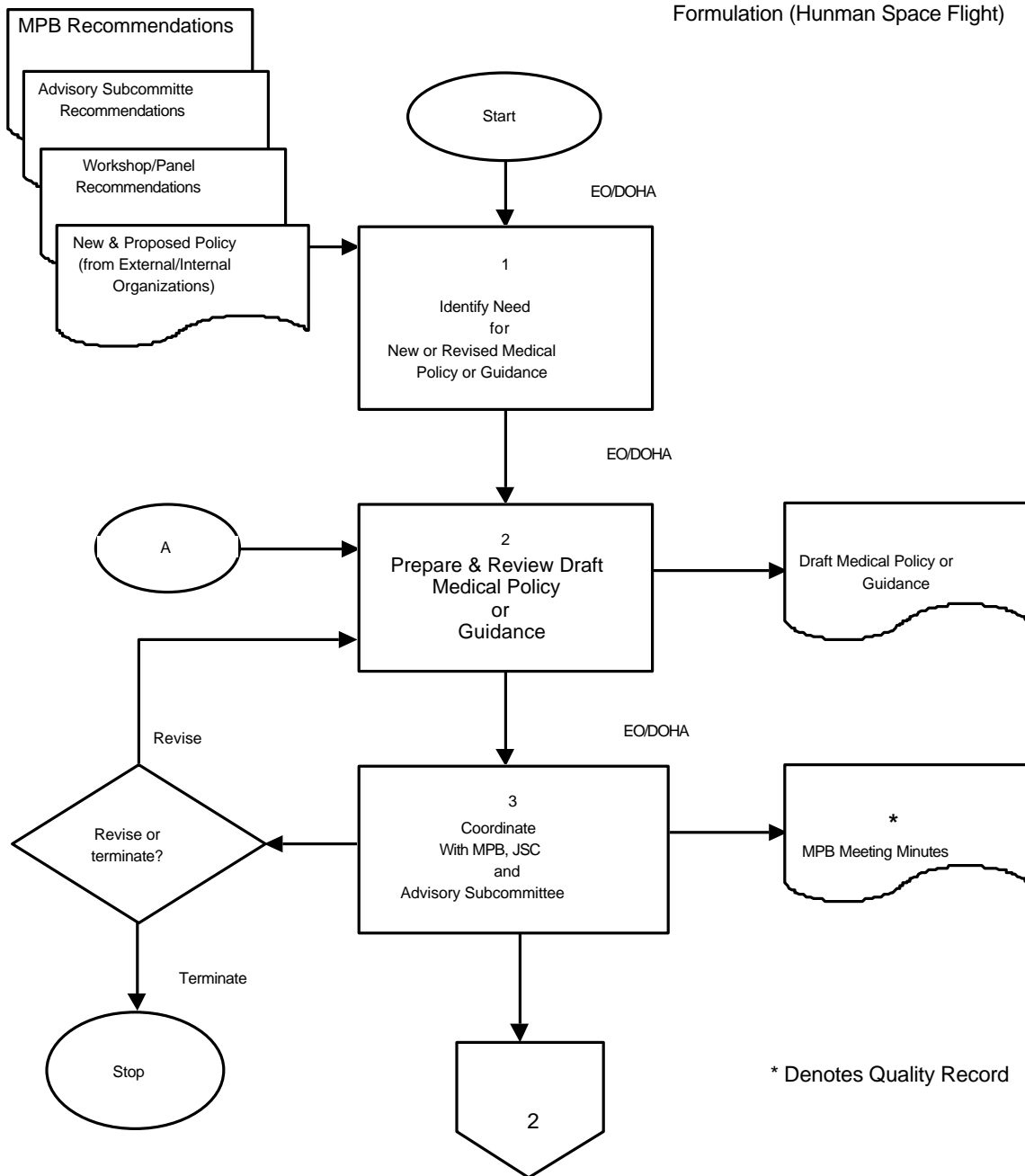
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5. Flowchart

Agency Medical Policy and Guidance
Formulation (Human Space Flight)



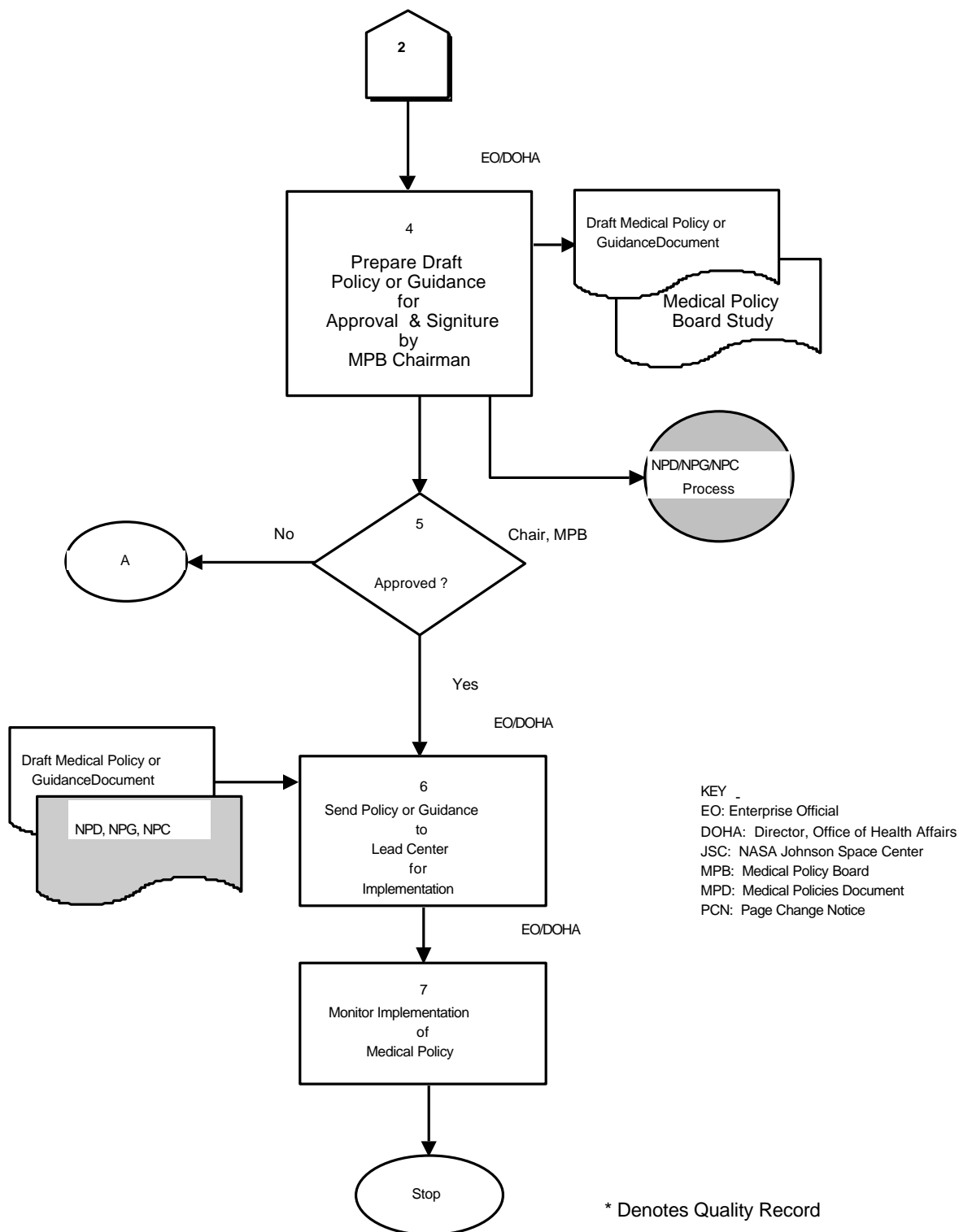
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6. Procedure

The number at the left of the process activity table refers to the flowchart step in Sec. 5.

#	Responsible Party	Activity Description
1	Enterprise Official or Director, Office of Health Affairs	<p>Identify the need for new or revised medical policy or guidance. The stimuli for new or revised policy or guidance may come from within NASA or from other organizations. A stimulus for action could include issues identified by the MPB, subcommittees of the NASA Advisory Committee, or expert workshops or panels, as well as new requirements on NASA because of new laws or regulations. Recommendations may also come from within the Office of Life and Microgravity Sciences and Applications (OLMSA) or other NASA staff involved in human space flight. The results of MPB studies are also an input.</p> <p>Present recommended actions for approval to the Chair, MPB. Recommendations could include revisions to existing MPD policies or formulation of new policies or guidance to include in the MPD. It could also be a recommendation to form an MPB working group to conduct a study. The new medical policy or guidance may be documented as a page change notice (PCN) to the MPD or included in a full revision of the MPD. If it is determined that no action is required, then there may be an output such as a note in the MPB minutes or an electronic mail message to MPB members indicating the outcome.</p>
2	Enterprise Official or Director, Office of Health Affairs	<p>If it is determined that new or revised policy or guidance is required, a draft is prepared and reviewed with the MPB Chair.</p> <p>Comments are incorporated and the draft policy/guidance is prepared for coordination outside of OLMSA. It is submitted to the MPB Executive Secretary who adds the topic to the agenda for review and approval at the next meeting of the MPB. If an MPD revision is prepared, then the draft is coordinated with MPB members before the MPB meeting.</p>

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|---|---|--|
| 3 | Enterprise Official or Director, Office of Health Affairs | Coordinate draft policy /guidance with MPB members, non-OLMSA staff involved in medical policy for human space flight and, as appropriate, with Advisory Subcommittee to obtain comments and approval. As needed, hold meeting of the MPB to review and approve the final policy/guidance. If a MPB meeting is held, comments and decisions are reflected in the <u>MPB Meeting Minutes</u> which are distributed to the MPB members. Return to Step 2 to revise policy to incorporate comments received during coordination. Repeat coordination, as required. If it is concluded that no new or revised policy is needed, terminate action.

If a study is to be performed, form ad hoc MPB working group. The working group produces the study and presents the results to the MPB. |
| 4 | Enterprise Official or Director, Office of Health Affairs | Prepare draft medical policy /guidance documents after coordination is completed. Present policy to the Chair, MPB for final approval and signature. If not approved, revise as required to obtain approval. Medical Policy Board Document rev. updated to reflect changes in medical policy.

Present studies for approval. Approved policy documentation requiring further processing to revise or create a new NPD, NPG or NPC are forwarded to the outside process governing approval of Agency policy procedures. If not approved, revise as required to obtain approval. |
| 5 | Chair, MPB | Review, approve and sign policy, guidance or study. If it is not approved go to step 2. |
| 6 | Enterprise Official or Director, Office of Health Affairs | Arrange for distribution of signed MPD revision or PCN to MPB members. |
| 7 | Enterprise Official or Director, Office of Health Affairs | Monitor implementation of medical policy. As appropriate, report to the MPB on the status of policy implementation. |

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<i>Record Identification</i>	<i>Owner</i>	<i>Location</i>	<i>Media Electronic/ Hard Copy</i>	<i>Schedule and Item Nos.*</i>	<i>Retention/ Disposition</i>
Medical Policy Board Meeting Minutes	Director, Code UH	Code UH	Hard Copy	Schedule 1, Item 14B.1	Permanent Retire to FRC when 2 years old. Transfer to NARA when 20 years old, whichever is sooner.

* Quality Records are retained in accordance with the referenced schedule and item number from NPG 1441.1,
NASA Records Retention Schedules